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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,166	01/12/2004	Mark B. Knudson	14283.1USI6	2117

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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,166	KNUDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *9-19 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 02/04, 04/04, 07/04, 08/04, 09/04, 01/05, 06/05, 08/05, 02/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Claims 1-8 and 20-23, in the reply filed on May 30, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on February 24, 2004, April 12, 2004, July 19, 2004, August 6, 2004, September 27, 2004, January 21, 2005, May 26, 2005, August 31, 2005 and February 2, 2006 have been acknowledged and are being considered by the Examiner.

Specification

3. The disclosure is objected to because of the following informalities: the "Cross-Reference to Related Applications" should be updated to include the serial numbers of the referenced Applications. Appropriate correction is required.

Claim Objections

4. Applicant is advised that should claim 4 be found allowable, claim 20 will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof. Also, should claim 5 be found allowable, claim 21 will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof and should claim 6 be found allowable, claim 22 will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof and further should claim 7 be found allowable, claim 23

will be objected to under 37 CFR 1 .75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 7-8, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Osorio et al. (U.S. 6,341,236) (herein Osorio). As to Claims 1-3, 7 and 23, Osorio discloses a method for treating epilepsy with minimized or no effect on the heart (see Osorio Abstract) comprising electrically stimulating a vagus nerve 60 of a patient at a stimulation site with a stimulation signal selected to have a therapeutic effect on a target organ (i.e. the brain) while applying an electrically blocking signal (i.e. anodal currents or high frequency stimulation) to the vagus nerve 60 at a blocking site (anode of the electrode pair) on a side of the stimulation site opposite the target organ (i.e. the brain) where the blocking signal is selected to at least partially block nerve impulses to a second organ (i.e. the heart 55) on a side of the blocking site opposite the stimulation site (cathode of the electrode pair) (see Osorio Figs. 12A-12B, column 6, lines 53-67 and column 7, lines 1-61).

7. As to Claims 4 and 20, Osorio further discloses that a signal generator 20 may be used to vary the pulsing parameters of the pulse signal applied to the vagus nerve 60 (see Osorio column 5, lines 13-34 and lines 47-54).

8. As to Claim 8, Osorio further discloses that the EKG may be monitored to determine that an involuntary movement is going to occur so that vagal nerve stimulation may be triggered and/or adjusted as necessary (see Osorio column 3, lines 61-63, column 8, lines 11-31 and column 12, lines 38-66).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 5-6 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio. Osorio discloses the claimed invention as discussed above except that it is not specified that the neural block be a cryogenic block or a pharmacologic block. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught Osorio with either a cryogenic block or a pharmacologic block, because Applicant has not disclosed that cryogenic blocks or pharmacologic blocks provide an advantage, are used for a particular purpose or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrical conductive block as taught by Osorio, because it provides a means for unidirectional nerve stimulation to treat a

disorder of interest while avoiding adverse side effects and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Osorio.

Therefore, it would have been an obvious matter of design choice to modify Osorio to obtain the invention as specified in the claim(s).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-7 and 20-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-13 and 17-19 of copending Application No. 10/674,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the claims of Application No. 10/674,324 or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claim 8 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-13 and 17-19 of copending Application No. 10/674,324 in view of Osorio. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the claims of Application No. 10/674,324 or an obvious variant thereof. Specifically, the claims of Application No. 10/674,324 include all of the limitations of the current claims except that it is not specified that the method further comprise the step of determining that an involuntary movement is going to occur and then applying the pulsed electrical signal to the vagus nerve. Osorio, however, discloses that the EKG may be monitored to determine that an involuntary movement is going to occur so that vagal nerve stimulation may be triggered and/or adjusted as necessary (see Osorio column 3, lines 61-63, column 8, lines 11-

31 and column 12, lines 38-66). It would have been obvious to one having ordinary skill in the art to modify the claims of Application No. 10/674,324 to include such limitations so that vagal stimulation is supplied at the opportune time.

This is a provisional obviousness-type double patenting rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rubin et al. (U.S. 6,369,079) teaches that use a pharmacologic blocks are well known in the art.

Lin (U.S. 6,558,708) teaches that it is well known to use a pharmacologic or cryogenic blocks.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel
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